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PATENT



DOCKET NO.: PHRM-0303/6225.N

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

Mark E. Gurney, et al.

Serial No.: 09/767,088

Group Art Unit: 1632

Filing Date: January 22, 2001

Examiner: Not Yet Assigned

For: TRANSGENIC MOUSE MODEL OF HUMAN NEURODEGENERATIVE
DISEASE

DATE OF DEPOSIT: January 4, 2002

I HEREBY CERTIFY THAT THIS PAPER IS BEING
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Robin S. Quartin
TYPED NAME: Robin S. Quartin, Ph.D.
REGISTRATION NO.: 45,028

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).



In accordance with §1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified application, within three months of the date of entry into the national stage of the above identified application as set forth in §1.491, before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first office action after the filing of request for continued examination under §1.114, no additional fee is required.

- ☐ In accordance with §1.129(a), this Information Disclosure Statement is being filed in connection with ☐the first or ☐second After Final Submission, therefore:
- ☐ Certification in Accordance with §1.97(e) is attached; or
- ☐ The fee of \$180.00 as set forth in §1.17(p) is attached.
- ☐ In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, or before an action that otherwise closes prosecution in the application, therefore:
- ☐ Certification in Accordance with §1.97(e) is attached; or
- ☐ The fee of \$180.00 as set forth in §1.17(p) is attached.
- ☐ In accordance with §1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311 but before, or simultaneously with, the payment of the Issue Fee, therefore included are: Certification in Accordance with §1.97(e); and the submission fee of \$180.00 as set forth in §1.17(p).
- ☒ Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.
- ☐ Copies of references listed on the attached Form PTO-1449 are enclosed herewith EXCEPT THAT:
- ☐ In view of the voluminous nature of references [list as appropriate], and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.

- ☐ In accordance with §1.98(d), copies of the following references listed on the attached Form PTO-1449 are not enclosed herewith because they were previously cited by or submitted to the U.S. Patent and Trademark Office in patent application(s) for which a claim for priority under 35 U.S.C. §120 have been made in the instant application:
- ☐ Copies of references [list as appropriate] listed on the attached Form PTO-1449 were previously cited by or submitted to the Patent and Trademark Office in prior application Serial No. , filed
- ☐ If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

Please charge any deficiency or credit any overpayment to Deposit Account No. 23-3050.

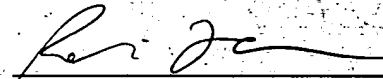
This form is submitted in duplicate.

Attached is a copy of the PCT Written Opinion dated December 6, 2001, which indicates the documents considered to be relevant.

There are no listed references which are not in the English language.

Date:

January 4, 2002


 Robin S. Quartin, Ph.D.
 Registration No. 45,028

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**WRITTEN OPINION
SEPARATE SHEET**

International application No. PCT/US01/01740

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Reference is made to the following documents:

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- D1: ZEHR C ET AL: 'Production and characterization of tau transgenic mice' SOC. NEUROSCI., vol. 25, 1999, page (A)447.1 XP001010369 cited in the application
- D2: BORCHELT D R ET AL: 'A vector for expressing foreign genes in the brains and hearts of transgenic mice' GENETIC ANALYSIS: BIOMOLECULAR ENGINEERING, US, ELSEVIER SCIENCE PUBLISHING, vol. 13, no. 6, 1 December 1996 (1996-12-01), pages 159-163, XP004017265 ISSN: 1050-3862
- D3: WO 99 57129 A (BROWN STUART M ;HEUTINK PETER (NL); GOATE ALISON M (US); MAYO FOUN) 11 November 1999 (1999-11-11)

The documents were not cited in the international search report. Copies of the documents are appended hereto.

- D4: Ishihara T. et al., 'Age-dependent emergence and progression of a tauopathy in transgenic mice overexpressing the shortest human tau isoform', NEURON vol. 24, pages 751-762, nov. 1999.
- D5: Lee V. M.-Y. and Trojanowski J.Q., 'Neurodegenerative tauopathies: human disease and transgenic mouse models', NEURON, vol.24, pages 507-510, nov. 1999.

Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

- 1.1 D1 discloses transgenic mice expressing the human Tau protein under the control of the mouse prion promoter. Four different constructs were used, they respectively encode isoforms with 3 repeats, 4 repeats, 3 repeats and the V337M mutation, and 4 repeats and the P301L mutation. Ubiquitous expression of the transgenic protein in the forebrain is observed.
- Therefore, D1 is prior art to the novelty of claims 1, 2, 4, 6, 9, 11 (Article 33(2) PCT).

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Sheet 1 of 1



Form PTO-1449 Modified

List of Patent and Publications
Cited by Applicant
(Use several sheets if necessary)

U.S. Department of Commerce
Patent and Trademark Office

Docket No.

PHRM-0303/6225.N

Serial No.

09/767,088

Applicant

Mark E. Gurney, et al.

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Group

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	AA	Ishihara, T. et al., "Age-dependent emergence and progression of a tauopathy in transgenic mice overexpressing the shortest human tau isoform", <i>Neuron</i> , 1999, 24, 751-762
	AB	Lee, V. M.Y. et al. "Neurodegenerative tauopathies: human disease and transgenic mouse models", <i>Neuron</i> , 1999, 24, 507-510
EXAMINER		DATE CONSIDERED